COMPRESSION APPARATUS

BACKGROUND

1. Technical Field

The present disclosure generally relates to the field of vascular therapy for application to a limb of a body, and more particularly, to a compression apparatus having removable portions.

2. Description of the Related Art

A major concern for immobile patients and persons alike are medical conditions that form clots in the blood, such as, deep vein thrombosis (DVT) and peripheral edema. Such patients and persons include those undergoing surgery, anesthesia, extended periods of bed rest, etc. These blood clotting conditions generally occur in the deep veins of the lower extremities and/or pelvis. These veins, such as the iliac, femoral, popiteal and tibial return deoxygenated to the heart. For example, when blood circulation in these veins is retarded due to illness, injury or inactivity, there is a tendency for blood to accumulate or pool. A static pool of blood is ideal for clot formations. A major risk associated with this condition is interference with cardiovascular circulation. Most seriously, a fragment of the blood clot can break loose and migrate. A pulmonary emboli can form blocking a main pulmonary artery, which may be life threatening.

The conditions and resulting risks associated with patient immobility may be controlled or alleviated by applying intermittent pressure to a patient's limb, such as, for example, a leg to assist in blood circulation. Known devices have been employed to assist in blood circulation, such as, one piece pads and compression boots. See, for example, U.S. Patent Nos. 6,290,662 and 6,494,852.

For example, sequential compression devices have been used, which consist of an air pump connected to a disposable wraparound pad by a series of air tubes. The wraparound pad is placed around the patient's leg. Air is then forced into different parts of the wraparound pad in sequence, creating pressure around the calves and improving venous return.

These known devices may suffer from various drawbacks due to their bulk and cumbersome nature of use. These drawbacks reduce comfort, compliance and may disadvantageously prevent mobility of the patient as recovery progresses after surgery.

Therefore, it would be desirable to overcome the disadvantages and drawbacks of the prior art with a prophylaxis sequential compression apparatus that reduces bulk and is not cumbersome during use to improve comfort and compliance to a patient. It would be desirable if the prophylaxis sequential compression apparatus includes a removable portion to achieve the advantages of the present disclosure. It would be highly desirable if the prophylaxis sequential compression apparatus has a valve connector that facilitates quick disconnect from a pressurized fluid source. It is contemplated that the prophylaxis sequential compression apparatus is easily and efficiently manufactured.

SUMMARY

Accordingly, a compression apparatus is provided that reduces bulk and is not cumbersome during use to improve comfort and compliance to a patient for overcoming the disadvantages and drawbacks of the prior art. Desirably, the compression apparatus includes a removable portion to achieve the advantages of the present disclosure. Most desirably, the compression apparatus has a valve connector that facilitates quick disconnect from a pressurized fluid source. The compression apparatus is easily and efficiently fabricated.

The compression apparatus, in accordance with the principles of the present disclosure, includes a thigh length compression sleeve that converts to a knee length sleeve via tearing away or otherwise removing the thigh bladder and disconnecting the thigh bladder air supply line. In one embodiment, the thigh bladder air supply line will remove easily along with the thigh bladder, attaching at or near the point where the thigh bladder is removed from the sleeve. This would allow for a single motion to accomplish both removing of the thigh bladder and the thigh bladder supply line. The convertible sleeve allows the patient to use a more comfortable sleeve (knee vs. thigh) as risk for DVT decreases after surgery. This provides practitioners with various options while using a single apparatus.

In another embodiment, the compression apparatus is perforated for improved compliance and comfort with the patient during the overall length of time for wearing the apparatus. It is contemplated that the apparatus can be used with both nomadic and/or stationary compression systems. A pressurized fluid source continues to deliver pressurized fluid after removal of the valve. The pressurized fluid source can signal a high alarm if there are kinks in the tubing and a low alarm if there are leaks in the tubing. The compression apparatus is sequentially activated by increasing pressure through the tubes to correspond with the three portions of the sleeve. The distal end is the ankle bladder (high pressure), the proximal end is the thigh bladder (low pressure). The pressurized fluid source pumps air to the sleeve in a 60 second cycle with 11 seconds being compression and the rest being decompression.

In one embodiment, in accordance with the principles of the present disclosure, the compression apparatus includes a sleeve configured for disposal about a limb. The sleeve includes a first portion defining a first expandable chamber and a second portion defining a second expandable chamber and a third expandable chamber. The second portion includes a connector in fluid communication with a pressurized fluid source and the first expandable chamber, the second expandable chamber and the third expandable chamber thereby facilitating fluid communication between the pressurized fluid source and the chambers. The first portion is removable from the second portion.

The first portion is connected to the second portion via a perforated attachment. The first portion may be configured for disposal about a first part of the limb and the second portion is configured for disposal about a second part of the limb. The second expandable chamber may be disposed with the second portion for disposal about a second part of the limb and the third expandable chamber is disposed with the second portion for disposal about a third part of the limb.

Alternatively, the compression apparatus can include a variety of welds and bladders forming a quilting effect. For example, the first, second and third expandable chambers can each define at least one sub-chamber.

The sleeve may define at least one ventilation opening. The at least one opening can include openings formed in a surface of the expandable chambers. The at least one opening may include a slit disposed between the second expandable chamber and the third expandable chamber.

The connector can communicate with the chambers via a tubular pathway. The tubular pathway of the first expandable chamber may be removable from the connector. A pressurized fluid may be delivered to the chambers for expansion thereof in a sequential time interval such that, for example, the first expandable chamber is expanded, followed by (2.5 seconds later) the second expandable chamber, followed by (3 seconds later) the third expandable chamber to a total of 11 seconds from the start of the first expandable chamber. The chambers are then all simultaneously vented to the atmosphere.

In an alternate embodiment, the compression apparatus includes a sleeve configured to wrap about a leg and defining a plurality of ventilation openings. The sleeve includes a thigh portion defining a first inflatable chamber having sub-chambers. The sleeve further includes a calf portion defining a second inflatable chamber having sub-chambers and an ankle portion defining a third inflatable chamber having sub-chambers. The ankle portion includes a valve connector that fluidly communicates both a pressurized fluid source and the chambers via a tubular pathway to facilitate inflation of the chambers. The thigh portion is removably connected to the calf portion via a perforated attachment and the tubular pathway of the first inflatable chamber is removable from the valve connector.

In an alternate embodiment, the compression apparatus includes an expandable sleeve that is configured for disposal about a leg. The sleeve extends a length from below a knee of the leg to above the knee. The sleeve is convertible from the length extending from below the knee to above the knee, to a length extending solely below the knee. The length of the sleeve extending from below the knee to above the knee may include a first portion disposed about a thigh of the leg, the first portion being removable from the sleeve. The first portion may be connected to the sleeve via perforations.

In one method, the ankle bladder is compressed for 2½ seconds, the mid-section bladder is compressed for 2½ seconds and the proximal section bladder is also compressed for 2 ½ seconds. After the 11th second elapses, all bladders are vented simultaneously. The thigh portion may be torn away, thereby converting from a full leg to a knee length. A ventilation slit is disposed on the back of the calf portion. This dissipates heat, relieves itching and accommodates movement. A knit or hosiery under the compressive sleeve may be used.

In an alternate embodiment, a method of performing compression on a limb of a body includes the steps of providing a sleeve configured for disposal about the limb, the sleeve includes a first portion defining a first inflatable chamber and a second portion defining a second inflatable chamber and a third inflatable chamber, the second portion includes a connector in fluid communication with a pressurized fluid source and the chambers thereby facilitating fluid communication between the pressurized fluid source and the chambers, the first portion is removable from the second portion; disposing the sleeve about the limb; delivering pressurized fluid to the first inflatable chamber; delivering pressurized fluid to the second inflatable chamber; delivering pressurized fluid to the third inflatable chamber; deflating the chambers; and removing the first portion from the second portion.

The steps of delivering may each be performed for a duration of 2.5 seconds. The step of removing may include disconnecting the first inflatable chamber from the connector. The step of removing can include tearing the first portion from the second portion via a perforated attachment.

In an alternate embodiment, a method of performing compression on a limb of a body includes the steps of providing an expandable sleeve configured for disposal about a leg; disposing the sleeve about the limb such that the sleeve extends a length from below a knee of the leg to above the knee; delivering pressurized fluid to the sleeve; deflating the sleeve; and converting the sleeve from the length extending from below the knee to above the knee, to a length extending solely below the knee. The step of disposing the sleeve about the limb such that the sleeve extends a length from below a knee of the leg to above the knee can include a first portion of the sleeve being disposed about a thigh of the leg. The step of converting may include tearing the first portion from the sleeve.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the present disclosure, which are believed to be novel, are set forth with the particularity in the appended claims. The present disclosure, both as to its organization and manner of operation, together with further objectives and advantages, may be best understood by reference to the following description, taken in connection with the accompanying drawings, which are described below.

FIG. 1 is a perspective view of one particular embodiment of a compression apparatus in accordance with the principles of the present disclosure;

FIG. 2 is a side cross-sectional view of a chamber of the apparatus shown in FIG. 1;

FIG. 3 is a top view of a connector of the apparatus shown in FIG. 1;

FIGS. 4A and 4B are perspective views of the apparatus shown in FIG. 1 disposed about a limb as well as a pressurized fluid source;

FIGS. 4C and 4D are perspective views of the apparatus shown;

FIGS. 5A and 5B are perspective views of the apparatus shown in FIGS. 4A-4D whereby a tubular pathway of a portion of the apparatus is removed from the connector;

FIGS. 6A and 6B are perspective views of the apparatus shown in FIG. 5 whereby a portion of the apparatus is removed;

FIG. 7 is a pressure versus time plot illustrating sequential compression of the apparatus shown in FIG. 1; and

FIG. 8 is an alternate embodiment of the compression apparatus shown in FIG. 1.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The exemplary embodiments of the compression apparatus and methods of operation disclosed are discussed in terms of vascular therapy including a prophylaxis compression apparatus for application to a limb of a body and more particularly in terms of a compression apparatus having removable portions. It is contemplated that the compression apparatus may be employed for preventing and overcoming the risks associated with patient immobility. It is further contemplated that the compression apparatus alleviates the conditions arising from patient immobility to prevent for example, DVT, peripheral edema, etc. It is contemplated that the compression apparatus according to the present disclosure may be attributable to all types of venous compression systems, including, but not limited to a prophylaxis sequential compression apparatus. The term "prophylaxis sequential" shall not be construed as limiting the general venous compression apparatus described herein. It is envisioned that the present disclosure, however, finds application with a wide variety of immobile conditions of persons and patients alike, such as, for example, those undergoing surgery, anesthesia, extended periods of bed rest, obesity, advanced age, malignancy, prior thromboembolism, etc.

In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a torso of a subject and the term "distal" refers to a portion that is further from the torso. As used herein the term "subject" refers to a patient undergoing vascular therapy using the compression apparatus. According to the present disclosure, the term "practitioner" refers to an individual administering the compression apparatus and may include support personnel.

The following discussion includes a description of the compression apparatus, followed by a description of an exemplary method of operating the compression apparatus in accordance with the principals of the present disclosure. Reference will now be made in detail to the exemplary embodiments and disclosure, which are illustrated with the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGS. 1 and 2, there is illustrated a prophylaxis sequential compression apparatus 10, constructed in accordance with the principals of the present disclosure. Compression apparatus 10 includes a sleeve 12 configured for disposal

about a limb, such as, for example, a leg L (FIGS. 4-6) of a subject's body. It is contemplated that sleeve 12 and other parts of compression apparatus 10 may be disposed, wrapped, mounted, etc., with various limbs, extremities, etc. of a subject's body, such as, for example, legs, arms, etc.

Sleeve 12 includes a first portion, such as, for example, thigh portion 14 that defines a first expandable chamber, such as, for example, first inflatable chamber 16. A second portion 18 of sleeve 12 defines a second expandable chamber, such as, for example, second inflatable chamber 20 and a third expandable chamber, such as, for example, third inflatable chamber 22. It is envisioned that the first portion 14 and the second portion 18 may include one or a plurality of expandable chambers. It is further envisioned that sleeve 12 or portions thereof may be disposable.

Second portion 18 has a calf portion 24 that includes second inflatable chamber 20 and an ankle portion 26 that includes third inflatable chamber 22. It is contemplated that the first portion and second portion 18 may be disposed about various portions of a subject's limb, according to the requirements of a particular vascular therapy application. Ankle portion 26 includes a valve connector 64 in fluid communication with a pressurized fluid source 30 via valve connector 28 and tubing 62 (FIGS. 4C and 4D) and chambers 16, 20 and 22 via a fluid pathway including tubing, as will be discussed below (see, for example, the valve connector described in U.S. Patent Application Serial No. --/---,---, filed on February 23, 2004 and entitled Fluid Conduit Connector Apparatus, the entire contents of which is hereby incorporated by reference herein). Tubing 62 is made up of three separate tubes or lumens 65A, 65B and 65C. This configuration facilitates fluid communication between pressurized fluid 30 and chambers 16, 20 and 22.

Thigh portion 14 is removable from second portion 18. For example, calf portion 24 is removably connected to thigh portion 14 via a perforated attachment 32, as will be discussed. This removable configuration advantageously reduces the bulk of compression apparatus 10 via facile manipulation to increase comfort and compliance to a subject. Compression apparatus 10 also provides a subject with increased mobility. It is envisioned that sleeve 12 may include

flexible sections, such as, elastic or spandex materials, disposed between the portions to facilitate mobility of a limb during use.

As best shown at FIGS. 1 and 2, sleeve 12 includes a top sheet 34 and a bottom sheet 36 that are overlaid to form the sleeve. Top sheet 34 and bottom sheet 36 are fixedly joined at seams that define inflatable chambers 16, 20 and 22. A seam 38 defines chamber 16, a seam 40 defines chamber 20 and a seam defines chamber 22. An edge 44 extends beyond seams 38, 40 and 42 about sleeve 12. It is contemplated that sleeve 12 includes a plurality of seams, disposed variously thereabout, that join top sheet 34 and bottom sheet 36. It is further contemplated that the seams may be welded, sewn, formed by adhesive, heat sealed, etc.

Top sheet 34 and bottom sheet 36 are fabricated from materials suitable for inflation of chambers 16, 20 and 22, such as, for example, films and fabrics, such as PVC (polyvinyl chloride) and PE (polyethylene), depending on the particular vascular therapy application and/or preference. Semi-flexible and flexible fabrics, such as urethanes and silicones may also be used. Sleeve 12 may include separate structure that include chambers 16, 20 and 22 and are disposed with or mounted to sheets 34, 36. One skilled in the art, however, will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

Sleeve 12 defines vent openings, such as, for example sleeve apertures 46 that provide cooling to an adjacent portion of the limb of the subject. Sleeve apertures 46 pass completely through top sheet 34 and bottom sheet 36. This advantageously improves comfort to the subject during use. Sleeve 12 includes a weld portion 48 that surrounds sleeve aperture 46 to seal off the respective chamber from the aperture and prevent fluid communication therebetween. Sleeve 12 also includes vent holes 47 to provide cooling. It is envisioned that sleeve 12 may include a plurality of vent openings disposed variously thereabout.

A vent opening, such as, for example, vent slit 50 is disposed between inflatable chamber 20 and inflatable chamber 22. Vent slit 50 passes completely through top sheet 34 and bottom sheet 36. The vent slit advantageously provides cooling to the subject and increases mobility of the calf and ankle during use. It is contemplated that vent slit 50 may extend various lengths.

Thigh portion 14 includes an axial line of spot welds 52 that define sub-chambers 54 of inflatable chamber 16. Calf portion 24 similarly includes an axial line of spot welds 54 that define sub-chambers 56 of inflatable chamber 20 and ankle portion 26 includes spot welds 58 that define sub-chambers 60 of inflatable chamber 22. It is envisioned the sub-chambers may be alternatively formed via a continuous weld, adhesive, hot seal, etc. It is further envisioned that welds 58 may be disposed in various orientations to create alternative configurations for the sub-chambers.

Valve connector 28 communicates with chambers 16, 20 and 22 via a fluid pathway. The fluid pathway includes tubing 62 that connects valve connector 28 to pressurized fluid source 30, which may include a pump (see, for example, the controller pump described in U.S. Patent Application Serial No. --/---,---, filed on February 23, 2004 and entitled Compression Treatment System, the entire contents of which is hereby incorporated by reference herein). Pressurized fluid source 30 may be stationary or portable. It is contemplated that pressurized fluid source 30 may include the necessary electronics, computer software, etc. to carry out vascular therapy, in accordance with the principles of the present disclosure.

Tubing 62 attaches to valve connector 28 via a coupler 64, as shown in FIG. 3. Tubing 66 extends from valve connector 28 and fluidly connects to inflatable chamber 20. Tubing 67 extends from valve connector 28 and fluidly connects to inflatable chamber 22. Tubing 68 extends from valve connector 28 and fluidly connects to inflatable chamber 16. Tubing 68 includes a quick disconnect port 70. Port 70 attaches with valve connector 28 and is easily removable to facilitate removal of thigh portion 14 from calf portion 24. Tubing 62 and lumens 65A, 65B and 65C correspond with tubes 67, 66 and 68, respectively. It is envisioned that valve connector 28 may be fixed with sleeve 12, removable, tethered, etc. It is further envisioned that port 70 may be fixed with valve connector 28 and tubing 68 is removable from thigh portion 14.

Sleeve 12 includes securing parts, such as, for example, hook and loop pads 72 mounted in an orientation for engagement with corresponding hook and loop pads 74. Hook and loop pads 72, 74 enable secure mounting of sleeve 12 with leg L of a subject. It is contemplated that one or a plurality of securing parts that may be variously disposed about sleeve 12. It is further contemplated that the securing parts may include for example, clips, adhesive, pins, etc.

Referring to FIGS. 4-7, compression apparatus 10, similar to that described above, is assembled, sterilized and packaged for use. In operation, compression apparatus 10 is provided and manipulated for disposal about leg L of the subject. Tubing 66 is connected with calf portion 24 and tubing 67 is connected with ankle portion 26. Tubing 68 is connected to thigh portion 14. Tubing 66, 67 and 68 is connected to valve connector 28, which is connected with tubing 62 and pressurized fluid source 30 (FIGS. 4C and 4D). Therefore, the fluid pathway of compression apparatus 10 establishes fluid communication between pressurized fluid source 30 and chambers 16, 20 and 22.

Sleeve 12 is wrapped about leg L and secured thereto via hook and loop pads 72, 74, discussed above, as shown in FIGS. 4A and 4B. Sleeve 12 extends a length from below a knee of leg L, via second portion 18, to above the knee, via thigh portion 14. Compression apparatus 10 is sequentially activated by delivering pressurized fluid to chambers 16, 20 and 22 via the fluid pathway. In one embodiment and as shown at FIG. 7, pressurized fluid source 30 delivers air to sleeve 12 in a 60 second cycle including 11 seconds in compression and 49 seconds in decompression. Compressed air is delivered to inflatable chamber 22 for 2.5 seconds. Then, compressed air is delivered to inflatable chamber 20 for 2.5 seconds. Compressed air is then delivered to inflatable chamber 16 for 2.5 seconds. Compression apparatus 10 maintains inflation for several seconds until the 11^{th} second and then chambers 16, 20 and 22 are deflated simultaneously. It is contemplated that this sequential compression may continue for a plurality of cycles, according to the requirements of a particular vascular therapy application. Other sequential compression cycles are also contemplated. It is envisioned that various forms of fluid may be delivered to sleeve 12, such as, for example, liquid, gases, etc.

After a desired period of time for sequential compression elapses, e.g., recovery time, etc. pursuant to the requirements of a particular vascular therapy application, thigh portion 14 may be removed from second portion 18. Thus, sleeve 12 is convertible from the length extending from below the knee to above the knee, to a length extending solely below the knee. Sleeve 12 is manipulated such that thigh portion 14 is removed and torn from calf portion 24 via perforations 32, as shown in FIGS. 6A and 6B. Port 70, connected to tubing 68, is easily manipulated to quick disconnect from valve connector 28, as shown in FIG. 5B. The remaining portion of

sleeve 12, second portion 18 including calf portion 24 and ankle portion 26, is stand alone and continues to operate as described above. This converts sleeve 12 from a full leg length apparatus to a knee length apparatus. Compression apparatus 10 may be employed to completion of a desired vascular therapy application. Other methods of use are also contemplated, for example, the thigh portion 14 may not be removed and remain with the sleeve 12.

As stated above, upon the optional removal of thigh portion 14, a user or practitioner disconnects tubing member 68 and disconnect port 70 from connector 28. Connector 28 (and optionally disconnect port 70) is configured such that upon separation of tube 68 from connector 28, a desired amount of fluid flow from fluid source 30 is continuously achieved through the connector 28. Such continued fluid flow is desirable to maintain continuity with the pressurized fluid source 30. That is, fluid flow adjustments to the fluid source 30 need not be made if a user or practitioner decides to remove thigh portion 14 from the compression apparatus 10. Even after removal of thigh portion 14, the pressurized fluid source 30 will continue to deliver the same amount of fluid and pressure through tubing 65C into connector 28 and out into the atmosphere.

Referring to FIG. 8, an alternate embodiment of compression apparatus 10 is shown. Sleeve 12, similar to that described above, includes thigh portion 14 and a second portion 118. Second portion 118 has a calf portion 124 and an ankle portion 126 that include an inflatable chamber 122. Pressurized fluid source 30 (FIG. 1) fluidly communicates with sleeve 12 via valve connector 28 and tubing 62 (FIG. 1). Valve connector 28 fluidly communicates with chambers 16 and 122 via separate tubes 68 and 166, respectively, for employment similar to that described above, including the optional removal of thigh portion 14 via perforations 32.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the tear away and removable features of the instant compression apparatus 10 may be employed with other compression apparatuses (see, compression apparatus described in U.S. Patent Application Serial No. --/---,---, filed on February 23, 2004 and entitled Compression Apparatus, the entire contents of which is hereby incorporated by reference herein). Therefore, the above description should not be construed as limiting, but merely as

exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.